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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,283	07/08/2003	Peter T. W. Cheng	LA0085 NP	9913

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EXAMINER	
AULAKH, CHARANJIT	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,283	CHENG ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 03/29/04 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19 are pending in the application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to compounds of formula of claim 1 where X and Q represent C, A represents (CH2)x2-O, the 5-membered ring between variables B and A represents 1, 2, 4 oxadiazole or 1, 2, 3 triazole, and Y represents COOH, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 548, subclass 131.

II. Claims 1-12 and 14-19, drawn to compounds of formula of claim 1 where X, Q, A, Y and 5-membered ring are other than defined above for group I, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 230+.

3. The inventions I and II as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of invention II prima facia obvious. Search required for e.g ; compounds of invention I in class 548, subclass 131 is not the same search required for e.g ; compounds of invention II in class 546, subclass 230+ and therefore, constitutes a burdensome search.

4. During a telephone conversation with the applicant's attorney, Mr. Burton Rodney on March 29, 2004, a provisional election was made with traverse to prosecute the

invention of group I (compounds of claim 13), claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. It is of note that group II is subject to further restriction based on the values of variables X, Q, A and 5-membered heteroaryl group in the future applications.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547 ; Wands,

In re, 858. F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast five of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

In the specification on first page, the applicants mention that the instant compounds modulate blood glucose levels, triglyceride levels, insulin levels and non-esterified fatty acid levels. However, modulation includes both increases and decreases in blood glucose levels, triglyceride levels, insulin levels and non-esterified fatty acid levels and therefore, compounds will have different utility based on the compounds in the specification have variable Y as –COOH group. There is not even a single compound exemplified where Y is other than-COOH group or any ester. There is no mention of any mechanism such as enzyme inhibition, receptor agonist/antagonist activity etc. for the instant compounds and therefore, can not rely upon the prior art knowledge where compounds having specific receptor agonist/antagonist activity are known to have some utility. The applicants mention several disease conditions in claims 15 and 16 which can be treated by the instant compounds. However, there are no working examples present to show how the instant compounds will have utility in treating all these disease

conditions. There is no teaching either in the specification or prior art showing effectiveness of the instant compounds in known animal models of any disease condition. The instant compounds of formual of claim 1 encompasses several hundreds of thousands of compounds based on the values of various variables and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to assess whether they increase or decrease blood glucose levels, triglyceride levels, insulin levels and non-esterified fatty acid levels, to demonstrate the effectiveness of the instant compounds in known animal models of all disease conditions listed in claims 15 and 16 and hence their utility.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-12 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, the terms –prodrug ester and stereoisomers – are indefinite since it is not clear which prodrug and stereoisomer is being reffered here and how are they prepared. There is not even a single example of either produg or stereoisomer in the specification. The applicants are suggested to delete these terms.

In independent claim 1, the applicants mention that groups –(CH2)x, (CH2)x1 etc. may be optionally substituted with 1, 2 or 3 substituents. However, these substituents are not defined.

In claim 1, the value of variable R3 defined as heteroaryl, cycloheteroalkyl is indefinite since the size of the ring, number and types of heteroatoms present in the ring are not defined.

In claim 15, the term ---related diseases--- is indefinite since these diseases are not defined and furthermore, it is not clear how are they related.

11. Claims 1-12 and 14-19 are objected as containing non-elected subject matter.

Allowable Subject Matter

12. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds directed to the elected group are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Hartman (U.S. Patent no. 5,741,796) discloses compounds 3-7 and 3-8 (see column 34) which are closely related to instant compounds. However, the compounds of Hartman differ from the instant compounds in having 1,3-diazole as a 5-membered ring instead of the instant 1, 2, 4-oxadiazole or 1, 2, 3-triazole ring and furthermore, there is no teaching, suggestion or motivation to modify the compounds of Hartman to prepare the instant compounds.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

C. S. Aulakh

Charanjit S. Aulakh
Primary Examiner
Art Unit 1625